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Award Number: W81XWH-11-2-0197

TITLE: Combat Stress and Substance Use Intervention

PRINCIPAL INVESTIGATOR: Janice M. Brown, Ph.D.

CONTRACTING ORGANIZATION:

RTI International Research Triangle Park, NC 27709-2194

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					nd operational stress reactions
					through substance use. These data
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three intervention	conditions: Wait-li	st control, Stress bri	ef intervention, or S	tress plus Subs	stance Use brief intervention. A
Web-based interve	ention provides a pr	rivate and convenier	nt approach and show	ıld facilitate ac	ccess to care by reducing the stigma
and common barri	ers associated with	seeking treatment.			
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1. Introduction and Objectives

In today's environment, decision makers who want to determine whether to adopt new health care interventions require evidence that the interventions make sense fiscally as well as medically. The estimated societal costs for returning veterans with PTSD or depression over the first 2 years after deployment are between \$4 billion and \$6.2 billion. The continued rise in health care costs could affect other Department of Defense (DoD) programs and could potentially affect areas related to military capability and readiness. Studies have examined the costeffectiveness of brief interventions (BIs) in civilian settings with regard to many behaviors and the consequences of behavior and have found BIs to be cost-effective. The objective of the study is to evaluate the effectiveness of two Web-based brief interventions (BIs) in reducing stress and substance use among postdeployment active duty and National Guard military personnel. One intervention will focus only on combat and operational stress reactions (COSRs), the other on COSRs plus substance use. The BIs will be compared to a wait list control group. The overriding objective of this research is to reduce stress reactions and substance abuse. These data are vital to understanding additional steps the military might take in addressing issues of behavioral health, such as developing new, more broadly focused treatment interventions, and starting additional prevention approaches and programs. In addition to providing outcome data, the research will provide information on the cost, cost-effectiveness, and cost-benefit of the interventions. The proposed intervention shifts the locus of care from treatment of illness to promotion of psychological health and resilience. The intervention uses an emerging approach (the Web) that is also based on active and effective programs that enhance combat effectiveness, organizational health, and overall well-being of warriors and families. Finally, in an era of financial accountability, it is important that studies document the resources needed to build and maintain interventions. Thus, the information from the cost study will be available to decision makers to appropriately budget for setting up and implementing the interventions.

2. Body

Activity 1. Develop Web-Based Assessment Materials (Months 1–3)

We have finalized all assessment materials including the baseline and follow-up surveys and programmed the Web-based assessment instruments. We have also written text for all participant messaging through the web-based system.

Activity 2. Prepare Recruitment and Marketing Materials (Months 1–3)

We have developed recruitment and marketing materials for the study including a poster and tri-fold brochure. We have had the materials review by our points of contact (POCs) and made revisions based on their feedback.

Activity 3. Prepare Intervention Materials (Months 1–5)

The Web-based intervention application has been adapted to include military-specific content (e.g., graphics, feedback on military-specific drinking norms based on our previous research), a military-oriented interface, graphics of younger adults, and an interactive goal-setting component. The full intervention consists of modules for assessment, individualized feedback, intervention materials, and goal setting. All intervention materials have been finalized.

Activity 4. Obtain Study Approvals (Months 1–12)

We have received Institutional Review Board (IRB) approval from RTI. The human subjects packet has been submitted to the Human Research Protections Office (HRPO). We were delayed in submitting these materials until the website was fully operational in order that IRB members can see that to which participants will be exposed.

Activity 5. Develop Web Site (Months 1–11)

We have developed a project Web site that includes the baseline and follow-up surveys, feedback documents, intervention materials, and also information on the nature of the program, including sponsorship, purpose, time requirements, benefits of participation, frequently asked questions, and myths and facts. We have also developed a schematic of the study flow for the project including event codes for each significant path along the model in order to track participants' progress as they go through the website. All web programming is complete.

Activity 6. Pilot Intervention (Months 11–13)

We have conducted a series of tests on the intervention to ensure smooth operation of all systems. Testing individuals were drawn from health care staff at our participating National Guard armories and multiple RTI staff. Data from the pilot testing will not be maintained or used for any analyses.

Activity 7. Participant Recruitment (Months 13–36)

Participant recruitment will begin as soon as all approvals are obtained (estimated as Month 25) and will continue through Month 38 of the project. Follow-up data collection will continue through Month 44. We have been significantly delayed in initiating participant recruitment and will likely request a one-year no-cost extension if the required number of participants have not been enrolled by Month 38.

3. Key Research Accomplishments

Accomplishments during Year 2 include the following:

- Finalized all survey assessments.
- Programmed and tested the survey.
- Finalized marketing materials.
- Finalized and programmed documents for frequently asked questions (FAQs) for both alcohol and stress.
- Finalized and programmed documents for myths and facts for both alcohol and stress.
- Recruited two armories and one active duty installation to be in the study.
- Initiated contact for approval at one additional state-level armory and one additional active duty site.
- Finalized and programmed feedback reports for alcohol and stress.
- Finalized and programmed brief interventions for alcohol and stress.
- Finalized and programmed all notifications for participants including: welcome message, ineligibility statements, group assignment statements, follow-up notifications, reminder emails, and holiday greetings.
- Submitted RTI IRB materials.
- Received RTI IRB approval.
- Submitted HRPO materials.
- Received HRPO approval 10/4/13.

4. Reportable Outcomes

There are no reportable outcomes at this time because this study has not yet received all approvals and data collection has not begun.

5. Conclusions

At this time there are no conclusions that can be made because the main study has not been conducted.

6. References

Not applicable

Appendix A: IPR Meeting Slides



Combat Stress and Substance Abuse Intervention

Janice M. Brown, PhD RTI International

Award Number(s): W81XWH-11-2-0197

Award Date(s): 9/15/11-9/14/15 Award Amount: \$1.884.551

Contract Officer Representative: Dr. Jay Shore

www.rti.org

RTI International is a trade name of Research Triangle Institute

Co-Investigators/Team

- · Laura Strange, PhD Co-Investigator
- Alex Cowell, PhD Economist
- Richard Zemonek Programmer
- Jason Williams Statistician
- Carrie Borst Project Manager

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Study Background/Rationale

- Combat and Operational Stress Reactions expected and predictable emotional, intellectual, physical, and/or behavioral reactions.
- Estimated 20% to 30% of US military personnel returning from combat operations report significant psychological symptoms (including COSRs).
- Studies with soldiers have found that symptoms increase 3 to 6 months after returning home.
- Perceived stigma often keeps personnel from seeking help.

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Solution - SUSTAIN

Substance Use and STress: An INtervention

- Intervention based on Motivational Interviewing (MI)
- Randomized, controlled trial of two web-based interventions with active duty and National Guard personnel
 - Stress Only Intervention
 - Stress plus Alcohol Intervention
- Intervention groups compared to a Delayed Feedback control group (intervention provided at 6-month follow-up)
- Cost analysis
 - Resources needed to put the interventions in place
 - Costs to maintain the interventions
 - Cost-benefit of the two interventions (Bang for your buck)
- Adjunct to those currently receiving help
- Supports those who do not seek help because of perceived stigma

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Research Questions/Hypotheses

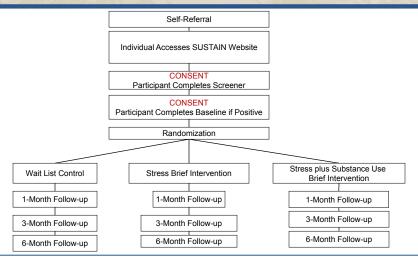
- **Hypothesis 1:** Both intervention groups will show reduction in COSRs over time compared with the wait list (WL) control group.
- Hypothesis 2: The stress plus substance use group (SSUBI) will show lower use of alcohol over time compared with the stress only group (SBI). Both groups will demonstrate lower substance use outcomes compared with the WL control group.
- Hypothesis 3: The SSUBI group will be cost-effective relative to SBI and WL groups.
- Additional Analyses: A number of individual-level factors (e.g., combat experiences, deployment history, unit cohesion) may interact with the interventions to attenuate responses to the interventions. These factors will be tested as moderators of the interventions' effectiveness. Factors that moderate effectiveness will help to identify for whom the interventions work.

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Study Design

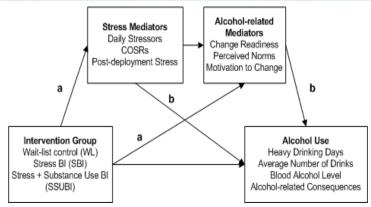


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Mediation Model of Program Effects

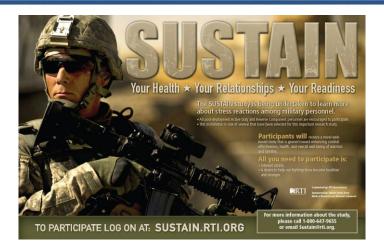


Point estimates for individual mediated effects (the effect of the intervention on a single outcome through a single mediator) will be estimated as ab, the product of the path from program to mediator ("a") and the path from mediator to an outcome ("b"). Significance of mediated effects will be tested with confidence intervals around ab formed with the bias-corrected bootstrap.

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Marketing Poster



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Current and Anticipated Challenges

IRB Delays

- Submission was contingent on a working website with full survey, feedback, and intervention components
- Resubmission to address potential risks with increasing symptoms
- Terminology concerns
- Engaging Sites
 - Currently in talks with Ft. Huachuca and WA ANG
 - IRB delays necessitate ongoing contact with recruited sites
- Next Steps
 - HRPO approval
 - Begin recruitment

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Study Progress to Date

- Marketing materials completed
- Survey assessments programmed and testing completed
- Feedback reports completed, programmed, and tested
- Interventions completed, programmed, and tested
- Two NG sites committed, third site in progress
- One active duty site committed, one site in progress
- RTI IRB approval received
- Documents submitted to HRPO

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Dissemination/Transition Plan

Transition

- Determine most effective intervention.
- Encourage ARNG to use/adopt effective arm and work to support adoption of the program (i.e., host website, train personnel).

Business

- Seek funding to conduct larger trial across all active duty components.
- Streamline interventions to focus on specific need.
- Refine/modify design to highlight findings from ARNG.

Dissemination

- Publish results in peer reviewed journals.
- Present findings at professional association meetings.
- Prepare briefing reports for sites to gauge ongoing interest.

10/2/2013

- Present briefings to DoD committees concerned with these issues.

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Appendix B: Study Marketing Materials



READY? VISIT SUSTAIN.RTI.ORG TO GET STARTED

or e-mail sustain@rti.org

Information

If you have questions about the study, participation, or your rights as a participant, please contact one of the following:

About the study:

Dr. Janice Brown, Principal Investigator 1-800-647-9655 jmbrown@rti.org

About how to participate:

Russ Peeler
SUSTAIN Site Coordinator
1-800-647-9655
rvp@rti.org

About your rights as a participant:

RTI Office of Research Protection, 1-866-214-2043 (toll free)

Visit
sustain.rti.org
to get started





SUSTAIN

Your Health

★
Your Relationships

★
Your Readiness



Conducted by: RTI International

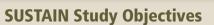
Sponsored by: United States Army Medical Research and Materiel Command

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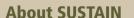
Your Health \star Your Relationships \star Your Readiness



The goal of the SUSTAIN program is to determine ways to better help members of the military deal with the effects of combat and operational stress



- to test the effectiveness of web-based education programs in reducing combat and operational stress reactions and other stresses among military service members
- to determine individual factors that may influence the effectiveness of these web-based programs
- to determine if these web-based education programs are a cost-effective way to help service members manage stress



The purpose of the SUSTAIN study is to test the effectiveness of two webbased programs in reducing combat and operational stress reactions in Active Duty and Reserve Component personnel.

Frequently Asked Questions



What does the SUSTAIN study involve?

Participating in the SUSTAIN education program will involve completing a series of questionnaires several times during the study. In addition, you will learn ways to manage your stress by setting realistic goals for yourself. YOUR ANSWERS TO ALL QUESTIONS ARE CONFIDENTIAL.

The SUSTAIN program is designed to determine if web-based stress management educational programs can help Active Duty and Reserve Component personnel reduce the various types of stress they experience. When you join the study, you may be assigned to one of the two groups that receives the web-based stress management education program immediately or to a group that receives the education program later when you complete the 6-month follow-up questionnaire.

YOUR PARTICIPATION IN SUSTAIN IS COMPLETELY CONFIDENTIAL. No one in your command will know that you are a participant. No identifying information will be published or reported about those who participate in the study.

How will SUSTAIN help Active Duty and Reserve Component personnel?

If successful, SUSTAIN may offer a number of benefits to those participating in the study. Potential benefits include:

- reduction of stress
- reduction in problems that can result from combat and operational stress and other stresses
- improved readiness, health, and wellness through the effective reduction of unhealthy behaviors

How long will the study take?

Once you are enrolled in the study, you will be randomly assigned to one of three groups. All groups will complete an initial questionnaire, which takes about 30 minutes, and three follow-up questionnaires, at 1, 3, and 6 months, each of which takes about 15 minutes. Two of the groups will also complete a 30-minute education program. If you are randomly assigned to one of the education groups, reviewing this material will take an additional 30 minutes. So your total time commitment will be no more than 2 and a half hours over 6 months.

Are there any risks?

There are no physical risks to taking part in the study. However, because the surveys will ask you questions about your military experiences and how you manage stress, you may find this emotionally uncomfortable at times. Participants who are made uncomfortable by any part of the program will receive a list of resources that can provide assistance.

Am I required to participate?

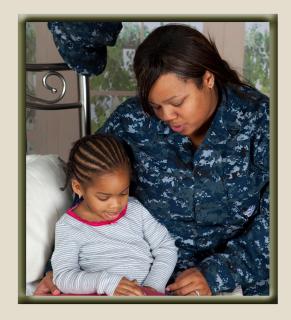
Your participation is voluntary. However, the input you and others provide is critical in determining if the program is effective. Hopefully the SUSTAIN program will help military members improve the ways they manage stress.

Will my information be kept confidential?

Identifying information about you or knowledge of your participation in the study will not be available to anyone outside of the research team, including your command. The answers we collect from you will be combined with answers from other participants so that it is impossible to identify any single participant. We will not publish any names or other identifying information in any reports or presentations.



Ready? Visit sustain.rti.org to get started.



What will I receive for participating?

You will receive a web-based education program that may help you better manage stresses—those related to your military service and those related to your relationships.

Who is conducting the SUSTAIN study?

The SUSTAIN program is funded by the United States Army Medical Research and Materiel Command. RTI International (RTI) is conducting this study. Headquartered in Research Triangle Park, NC, RTI is a leading independent, nonprofit institute that provides innovative scientific research and technical solutions for government, military, and business clients worldwide.